

Appl. No. : 10/620,312  
Filed : July 14, 2003

## REMARKS

### Pending Claims

Claims 1-6 remain pending in the application. Claim 1 has been amended to remove language associated with producing a controlled change in transmembrane potential. Although this is broad language, the language has been the focus of correspondence between the Examiner and the applicant in related applications with reference to claims that include other limitations. The applicant wishes to avoid any implication that those discussions are applicable to the present claim set.

### Provisional Double Patenting Rejections

The Examiner has provisionally rejected Claims 1-6 on the ground of nonstatutory obviousness-type double patenting in light of Claims 1-8, 10-29, 49 and 50 of co-pending application no. 09/804,457 ("the '457 application"). The present application is a continuation-in-part of the 09/804,457 application. Applicants do not believe that this provisional rejection is appropriate for the particular application and claims cited by the Examiner.

Furthermore, the 09/804,457 application published on April 18, 2002 as U.S. Publication Number 2002-0045159. The Examiner asserts that the currently pending claims are not supported by the 09/804,457 application and thus have an effective filing date of July 14, 2003, more than one year after the publication of the 09/804,457 application. The applicants respectfully submit that even if the 09/804,457 application is prior art to the present claims for all it teaches throughout its specification, the pending claims of this application are patentable over this reference for at least the same reasons discussed below with reference to the applied art of Sinha.

The applicant's request that the Examiner withdraw the double patenting rejection.

### Rejections under § 112 ¶ 1

The Examiner rejected Claims 1-6 under 35 U.S.C. § 112 ¶ 1 as being unpatentable. The Examiner stated that "because the specification [of the present application] while being enabling for a method claimed where the field strength is 0.2% of the mean, does not reasonably provide enablement for a method claimed where the field strength is greater than 0.2% of the mean. . . .

[T]he specification teaches that [an] electric field strength [] greater than 0.2% of the mean is enabled [], whereas the electric field of 10% of the mean is not acceptable.” More specifically, the Examiner states that “the specification [of the instant application] teaches that the electric field strength [] greater than 0.2% is enabled (page 97 of the specification) whereas the electric field of 10% [or greater] of the mean is not acceptable (page 96, line 10 of the specification.”

Applicants agree the specification teaches producing a variation in electric field greater than 10% from a mean intensity (in particular where the standard deviation of the field strength is 15% of the mean in the total area of observation as illustrated on page 96 of the specification)” is not ideal. Nevertheless, the specification enables a “producing a limited spatial variation in intensity in [an] electric field in [an] area of observation of **within**  $\pm 10\%$  from a mean intensity in that area.” (emphasis added) See, e.g., Example 1 page 95 (“the electric field remains within  $\pm 10\%$  of the mean field in the area of observation[, which] geometry satisfies the stated requirements for field uniformity for use in the present invention”), Example 3 pages 96-97 (“the electric field remains within  $\pm 1\%$  of the mean field in the area of observation[, which] geometry greatly improves the field uniformity”), Example 4 page 97 (“the electric field remains within  $\pm 1\%$  of the mean field in the area of observation[, which] geometry greatly improves the field uniformity”), Example 5 page 98 (“the difference between the maximum and minimum fields is 1.2% of the mean[, which] geometry greatly improves the field uniformity”) and Figures 7A, 8A, 8B and 8C. Applicants thus argue that Claim 1 is enabled by the disclosure provided in the specification and request withdrawal of the Examiner’s rejection of Claim 1 (and the claims that depend therefrom) for lack of enablement.

#### **Rejection of Claims 1-6 under § 102(b)**

The Examiner has rejected Claims 1-6 under 35 U.S.C. § 102(b) as anticipated by Sinha et al. (1995) (hereinafter “Sinha”). “A claim is anticipated [under § 102(b)] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P. § 2131 (quoting *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

Claim 1 recites “[a] method of characterizing the biological activity of a candidate compound comprising . . . exposing [a] population of cells to electric fields to produce a

controlled change in transmembrane potential of said population of cells, wherein said electric fields comprise a first pulse series and a second pulse series with a pause between the first pulse series and the second pulse series and monitoring changes in the transmembrane potential of said population of cells during at least a portion of said first pulse series and a portion of said second pulse series.”

Sinha does not disclose all of the elements of Claim 1. Nowhere does Sinha disclose “electric fields compris[ing] a first pulse series and a second pulse series with a pause between the first pulse series and the second pulse series” as recited in Claim 1. Sinha discloses stimulating hippocampal cells with pulsed electric field potentials. Sinha shows two individual pulses separated by 50 milliseconds, not two pulse series separated by a pause. See e.g., Figure 4 and pages 55-56 of Sinha. Thus, Sinha does not disclose all of the elements of Claim 1.

The methods of Claim 1 can be used to characterize the recovery of voltage-gated ion channels from voltage inactivation and from blockage by channel blockers. Some examples of such embodiments are found in Figures 34-37 of the present application and at ¶ [0516] of the present application.

Applicants respectfully request that the Examiner’s rejection of Claim1 and the claims dependent therefrom be withdrawn.

### CONCLUSION

The Applicants have endeavored to address all of the Examiner’s concerns as expressed in the outstanding Office Action. Accordingly, arguments in support of the patentability of the pending claim set are presented above. In light of these remarks, reconsideration and withdrawal of the outstanding rejections is respectfully requested.

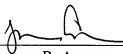
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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